AMENDMENTS TO THE CLAIMS

1. **(Currently Amended)** A method of producing ultrafine drug particles having an average particle size of 10 nm to 1000 nm, comprising the steps of 1) dissolving a drug in at least one good solvent or a mixture of good solvents to prepare a drug-containing solution; 2) mixing the drug-containing solution with a solvent being a poor solvent or a mixture of poor solvents for the drug and being miscible with the drug-containing solution in the good solvent or a mixture of good solvents; and 3) subjecting the prepared mixture directly to emulsification under a set processing pressure using [[a]] a Microfluidizer or Nanomiser without carrying out any pretreatment step for adjusting the drug to have an average particle size of 100 μm or less,

further comprising the steps of circulating the solvent being a poor solvent or a mixture of poor solvents for the drug and being miscible with the drug-containing solution in the good solvent or a mixture of good solvents through a channel in the Microfluidizer or Nanomiser and adding the drug-containing solution to the circulating miscible solvent to thereby mix them,

wherein the Microfluidizer or Nanomiser is equipped with an online injector and the Microfluidizer or Nanomiser comprises a reservoir, a booster pump and an emulsifier, being connected via thin tubes, the injector being so configured as to feed a drug-containing solution containing a drug dissolved in a good solvent or a mixture of good solvents, the injector being integrated into the Microfluidizer or Nanomiser at any position of the channel for the circulating fluid in the thin tubes extending from the reservoir to the emulsifier.

2. **(Canceled)**

3. **(Previously Presented)** The production method according to Claim 1, wherein the drug is an insoluble drug having a solubility in water of 1 mg/ml or less.

4. **(Previously Presented)** The production method according to Claim 1, further comprising dissolving a dispersing agent in a solvent of at least one of 1) the drug-containing solution in a good solvent or a mixture of good solvents and 2) the solvent being a poor solvent or a mixture of poor solvents for the drug and being miscible with the drug-containing solution in the good solvent or a mixture of good solvents.

5. **(Previously Presented)** The production method according to Claim 1, wherein a concentration of the dispersing agent in the solvent in which the dispersing agent is dissolved is 0.01% to 50% (W/V).

6. **(Previously Presented)** The production method according to Claim 1, wherein the dispersing agent is polyoxyethylene polyoxypropylene glycol, lecithin, gelatin and/or polyvinylpyrrolidone.

7. **(Previously Presented)** The production method according to Claim 1, wherein, in the step of mixing the drug-containing solution with a solvent being a poor solvent or a mixture of poor solvents for the drug and being miscible with the drug-containing solution in the good solvent or a mixture of good solvents, the amount of the drug-containing solution is 0.01% to 50% (V/V) to the amount of the solvent being a poor solvent or a mixture of poor solvents for the drug and being miscible with the drug-containing solution.

8. **(Previously Presented)** The production method according to Claim 1, wherein the average particle size is 100 nm to 400 nm.

9. **(Previously Presented)** The production method according to Claim 1, wherein the Microfluidizer is used.

10. **(Previously Presented)** The production method according to Claim 1, wherein the Nanomiser is used.

11. **(Previously Presented)** The production method according to Claim 1, wherein the drug is one of antitumor drugs, antibiotics, anti-inflammatory drugs, analgesics, drugs for treating osteoporosis, hypolipidemic drugs, antibacterial drugs, sedative drugs, tranquilizers, antiepileptic drugs, antidepressants, drugs for treating digestive system diseases, drugs for treating allergic diseases, antihypertensive drugs, antiarteriosclerosis drugs, antidiabetic drugs, hormone drugs and lipid soluble vitamin preparations.

12. **(Canceled)**

13. **(Previously Presented)** The production method according to Claim 1, wherein the Microfluidizer is used at a set processing pressure of 1000 to 6000 psi.

14. **(Previously Presented)** The production method according to Claim 1, wherein the Nanomiser is used at a set processing pressure of 6000 to 20000 psi.

15. **(Previously Presented)** A method of producing a suspension of ultrafine drug particles or powdered ultrafine drug particles in an arbitrary concentration, the ultrafine drug particles having an average particle size of 10 nm to 1000 nm, comprising the steps of 1) dissolving a drug in a good solvent or a mixture of good solvents to prepare a drug-containing solution; 2) mixing the drug-containing solution with a solvent being a poor solvent or a mixture

of poor solvents for the drug and being miscible with the drug-containing solution in the good solvent or a mixture of good solvents; 3) subjecting the prepared mixture directly to emulsification under a set processing pressure using a Microfluidizer or Nanomiser without carrying out a pretreatment step for adjusting the drug to have an average particle size of 100 μm or less; and 4) removing part or all of the solvent from the suspension of ultrafine drug particles after the treatment with the Microfluidizer or Nanomiser,

further comprising the steps of circulating the solvent being a poor solvent or a mixture of poor solvents for the drug and being miscible with the drug-containing solution in the good solvent or a mixture of good solvents through a channel in the Microfluidizer or Nanomiser and adding the drug-containing solution to the circulating miscible solvent to thereby mix them,

wherein said Microfluidizer or Nanomiser is equipped with an online injector and the Microfluidizer or Nanomiser comprises a reservoir, a booster pump and an emulsifier, being connected via thin tubes, the injector being so configured as to feed a drug-containing solution containing a drug dissolved in a good solvent or a mixture of good solvents, the injector being integrated into the Microfluidizer or Nanomiser at any position of the channel for the circulating fluid in the thin tubes extending from the reservoir to the emulsifier.

16. **(Canceled)**

17. **(Previously Presented)** The production method according to Claim 15, wherein the step of removing part or all of the solvent from the suspension of ultrafine drug particles after the treatment with the high-pressure homogenizer is freeze-drying.

18. **(Withdrawn)** A high-pressure homogenizer equipped with an online injector, comprising a high-pressure homogenizer and an injector, the high-pressure homogenizer shown in the following Fig. 1 comprising a reservoir, a booster pump and an emulsifier, being connected via thin tubes, the injector being so configured as to feed a drug-containing solution containing a drug dissolved in a good solvent or a mixture of good solvents, the injector being integrated into the high-pressure homogenizer at any position of a channel for a circulating fluid in the thin tubes extending from the reservoir to the emulsifier.

19. **(Withdrawn)** The high-pressure homogenizer equipped with an online injector according to Claim 18, wherein the injector is integrated at any position of a channel in the thin tube connecting between the reservoir and the booster pump as shown in the following Fig. 2.

20. **(Withdrawn)** The high-pressure homogenizer equipped with an online injector according to Claim 18, wherein the injector is integrated at any position of a channel in the thin tube connecting between the booster pump and the emulsifier as shown in the following Fig. 3.

21. **(Withdrawn)** The high-pressure homogenizer equipped with an online injector according to Claim 18, wherein the injector is integrated at any position of a channel in the thin tubes via a joint and/or a mixer.

22. **(Withdrawn)** The high-pressure homogenizer equipped with an online injector according to Claim 18, further comprising a regulator for controlling the temperature of the circulating fluid and/or the drug-containing solution, the regulator being integrated into part or all of the emulsifier and/or the thin tubes.

23. **(Canceled)**

24. **(Currently Amended)** A method of producing ultrafine drug particles having an average particle size of 10 nm to 1000 nm, comprising the steps of

1) dissolving a drug in a good solvent or a mixture of good solvents to prepare a drug-containing solution; 2) circulating a solvent in a channel for a circulating fluid in thin tubes of [[a]] a Microfluidizer or Nanomiser equipped with an online injector, wherein the Microfluidizer or Nanomiser comprises a reservoir, a booster pump and an emulsifier, being connected via the thin tubes, the injector being so configured as to feed a drug-containing solution containing a drug dissolved in a good solvent or a mixture of good solvents, the injector being integrated into the Microfluidizer or Nanomiser at any position of the channel for the circulating fluid in the thin tubes extending from the reservoir to the emulsifier, and the solvent being a poor solvent or a mixture of poor solvents for the drug and being miscible with the drug-containing solution in the good solvent or a mixture of good solvents; 3) feeding the drug-containing solution through the online injector to thereby mix the drug-containing solution with the circulating miscible solvent; and 4) directly emulsifying the resulting mixture online under a set processing pressure using the Microfluidizer or Nanomiser.

25. **(Canceled)**